MAR 15 2006

K052555
page 1 of 3

APPENDIX I

510(k) Summary

Medtronic Performer CPB System

(As required by 21CFR 807.92)

A. Submitter Information

Submitter's Name:	RanD S.r.l.
Address:	Via Sparato, 60 41036 Medolla (MO) – ITALY
Telephone Number:	763.391.9533 (for contact)
Contact Person:	Preeti Jain
Date Submission Prepared:	September 15, 2005

B. Device Information

Trade Name	Performer Cardiopulmonary Bypass System
Common Name	Cardiopulmonary bypass heart-lung machine console
Address of Manufacturing Facilities	*Manufacturing Site* RanD S.r.l. Via Sparato, 60 41036 Medolla (MO) – ITALY Establishment Registration Number Pending
FDA Classification	Class II
FDA Product Classification Code	DTQ
FDA Regulation Number	21 CFR 870.4220
FDA Classification Panel	Cardiovascular

Predicate Devices:

- COBE Century Perfusion Pump (K960974)
- Terumo Advanced Perfusion System 1 (K022947)

The Performer CPB has incorporated capabilities from five stand alone Medtronic devices which are:

- Medtronic Resting Heart System (K031700)

- Medtronic 560 BioConsuole System (K051303)
- Medtronic Oxygen Saturation and Hematocrit System (K954501)
- CSS Cardioplegia Safety System (K973237)
- Medtronic Pressure Display Box and Tubing Set (K852232)

Device Description:

The Performer CPB, is a next generation heart lung machine that integrates the primary functions and safety features needed to perform cardiopulmonary bypass and related circulatory support procedures, along with enhanced user conveniences, into a reduced sized instrument. The product is designed and manufactured by RanD S.r.l., Medolla, Italy for Medtronic and exclusively distributed by Medtronic Perfusion Systems.

It's initial configuration and features are optimized for use with the Medtronic Resting Heart System (K03170).

The key differences between the competitive heart lung machines and the Performer CPB are:

- A small foot print for the machine and pump's layout optimized (vertical orientation) for extracorporeal volume reduction. Collapsible feature for storage and easy transportation.
- Electrically adjustable height and stability system.
- Integrated Active Air Removal System.
- A built in printer.
- Pre configured roller pump rotation (unidirectional) and built in Handcrank in roller pumps for emergencies.
- Integrated "Memory Card" for treatment data recording and software updates.
- Integrated SatO2/Hct and Temperature monitoring system.
- Cardioplegia delivery air detector with pump stop feed back.
- Selectable alert/alarm tones (including voice).
- Active Air removal with arterial flow servo control.
- Predominant 'icon' based GUI.
- Independent status colored LED system (traffic light style) for alerts and alarms in addition to the audio and visual set ups on the actual user interface screen.

K052555
page 3 of 3

- Roller pump cover sensors.
- Real time integrated parameters' trending.

Indications for Use:

The Medtronic Performer CPB Advanced Extracorporeal Circulatory Support System is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in pumping blood through an extracorporeal perfusion circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours).

C. Comparison of Required Technological Characteristics

Medtronic Performer CPB System is a system comprised of standard components of an extracorporeal circuit for use during cardiopulmonary circulatory support. The system has the same technological characteristics as a traditional circuit and the single components have the same technological characteristics as the predicate.

D. Performance Data

Performance data, such as, air handling capabilities, blood trauma, cardioplegia delivery have been provided in the 510(k) submission to show equivalence of the Medtronic Performer CPB System, when working with Resting Heart Disposable Module to COBE Century System and other referenced devices. In addition comprehensive testing has been completed on the machine including performance and Software Verification and Validation.

E. Conclusion

Medtronic Performer CPB System is substantially equivalent to the noted predicate devices based on the similarities of technological characteristics, indications for use and the results of performance comparative testing and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Rand S.R.L.
c/o Ms. Preeti Jain
Director, Regulatory/Clinical Affairs
7611 Northland Drive
Minneapolis, MN 55428

Re: K052555
Performer CPB Heart Lung Machine
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart Lung Machine Console
Regulatory Class: Class II (Two)
Product Code: DTQ
Dated: March 3, 2006
Received: March 6, 2006

Dear Ms. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix II

Indications for Use

510(k) Number (if known): K052555

Device Name: Performer CPB

Indications For Use:

The Medtronic Performer CPB Advanced Extracorporeal Circulatory Support System is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in pumping blood through an extracorporeal perfusion circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours).

Prescription Use __X____ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052555